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U.S. DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BEVERLY HYDE, as widow and Executrix of the Estate of GERALD HYDE

Plaintiff,

v.

Civil Action No. 09 CA 10270 PBS

GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; GE HEALTHCARE AS; BAYER HEALTHCARE PHARMACEUTICALS, INC. f/ka BERLEX, INC., f/k/a BERLEX LABORATORIES, INC.; BAYER AG; BAYER SCHERING PHARMA AG f/k/a SCHERING AG; MALLINCKRODT, INC.; BRACCO DIAGNOSTICS INC.; BRACCO RESEARCH USA, INC.; ALTANA PHARMA AG; and NYCOMED INTERNATIONAL MANAGEMENT GmbH,

Defendants.

COMPLAINT AND JURY DEMAND

Plaintiff, by and through her counsel, BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C., and BRENT COON and ASSOCIATES, L.C., and for her Complaint against Defendants, alleges as follows:

PARTIES

1. Beverly Hyde is the widow and Executrix of the Estate of Gerald Hyde, of 175 Sea Street, Dennisport, MA 02639.

2. Defendant General Electric Company is a New York Corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. Defendant General Electric Company is a resident of both New York and Connecticut. Defendant General Electric Company is the parent company of Defendant GE Healthcare AS and GE Healthcare, Inc.

3. Defendant GE Healthcare AS is a Norwegian corporation with its principal place of business in the Kingdom of Norway. Defendant GE Healthcare AS is a subsidiary of General Electric Company. Omniscan's package insert/prescribing information identifies the putative manufacturer of Omniscan as GE Healthcare AS.

4. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey 08540.

5. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey.

6. Defendant GE Healthcare, Inc. is a subsidiary of General Electric Company. Omniscan's package insert identifies the putative distributor of Omniscan as GE Healthcare, Inc.

7. Defendants General Electric Company, GE Healthcare, Inc., and GE Healthcare AS will be collectively referred to in this Complaint as the "GE Defendants."

8. Defendant Bayer Healthcare Pharmaceuticals, Inc. f/k/a/ Berlex, Inc. f/k/a Berlex Laboratories, Inc., is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey 07470.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. f/k/a/ Berlex, Inc. f/k/a Berlex Laboratories, Inc. is a division of Bayer AG.

10. Defendant Bayer AG is a company domiciled in Germany and is the parent/holding company of both Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG.

11. On April 4, 2007, Berlex, Inc. f/k/a Berlex Laboratories, Inc. changed its name to Bayer Healthcare Pharmaceuticals, Inc.

12. Therefore, Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex, Inc. f/k/a Berlex Laboratories, Inc. and, as such, is obligated for its predecessor's liabilities.

13. Defendant Bayer Schering Pharma AG is a foreign company domiciled in Germany. Bayer Schering Pharma AG is a corporate successor to Schering AG. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

14. Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Schering Pharma AG will be collectively referred to in this Complaint as the "Bayer Defendants."

15. Defendant Mallinckrodt, Inc. ("Defendant Mallinckrodt") is a Delaware corporation with its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri 63042. Defendant Mallinckrodt is a resident and citizen of both Delaware and Missouri. Defendant Mallinckrodt is a subsidiary of Tyco Healthcare Group LP.

16. Defendant Bracco Diagnostics Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey.

17. Defendant Bracco Research USA, Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey.

18. Upon information and belief, Defendant ALTANA Pharma AG is a German company with its principal place of business in Germany.

19. Defendant ALTANA Pharma AG manufactured MultiHance and/or ProHance for Bracco Diagnostics Inc.

20. Defendant Nycomed International Management GmbH ("Nycomed") is a Swiss company domiciled in Switzerland. Defendant Nycomed bought ALTANA Pharma AG in 2006.

21. Defendant Nycomed is corporate successor to ALTANA Pharma AG and, as such, is obligated for its predecessor's liabilities.

22. Defendants Bracco Diagnostics Inc., Bracco Research USA, Inc., ALTANA Pharma AG and Nycomed will be collectively referred to in this Complaint and Jury Demand as the "Bracco Defendants."

JURISDICTION AND VENUE

23. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

24. The Court has personal jurisdiction over Defendants consistent with the laws of the State of Massachusetts and the United States Constitution because Defendants caused tortious injury in the State of Massachusetts by an act or omission outside the State of Massachusetts by virtue of Defendants' regularly conducted business in the State of Massachusetts from which they derive substantial revenue.

25. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Gerald Hyde was administered the offending contrast dye at Massachusetts General Hospital in Boston, Massachusetts in this district and acts and omissions occurred as the result of the administration of that contrast dye. All manifestation of the injury also took place in this district.

GENERAL ALLEGATIONS

26. This is a personal injury claim relating to Gerald Hyde's development of, and subsequent death from, Nephrogenic Systemic Fibrosis ("NSF"), also known as Nephrogenic Fibrosing Dermopathy ("NFD").

27. NSF/NFD develops only in patients with renal insufficiency, such as Gerald Hyde, who have been given an injection of a gadolinium-based contrast agent such as Magnevist, Omniscan, OptiMARK, and/or upon information and belief, MultiHance and/or ProHance.

28. NSF/NFD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within weeks after receiving a gadolinium-based

contrast injection such as Magnevist, Omniscan, OptiMARK and/or upon information and belief, MultiHance and/or ProHance.

29. These symptoms can occur weeks or months after a person is administered these dyes.

30. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in painful and disfiguring contractures.

31. NSF/NFD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints.

32. The skin changes that begin as darkened patches or plaques progress to a "woody" texture, and are accompanied by burning, itching, or severe pain in the areas of involvement.

33. NSF/NFD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death.

34. NSF/NFD is a progressive disease for which there is no known cure.

35. NSF/NFD has been reported in medical literature since 2000.

36. It has always been the case that this clinical entity now known as NSF/NFD develops in patients with renal insufficiency who have been given an injection of gadolinium-based contrast agent such as Omniscan, Magnevist, OptiMARK, MultiHance, and/or ProHance.

Omniscan and the GE Defendants

37. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography.

38. Omniscan contains the metal gadolinium, which is highly toxic in its free state.

39. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by the GE Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

40. Omniscan is cleared from the body solely by glomerular filtration in the kidneys.

41. As a result, Omniscan has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Omniscan administration.

42. Omniscan was originally developed by Salutar, Inc. which then conducted pre-clinical testing with Sterling Winthrop and Daiichi Pharmaceuticals.

43. Salutar was subsequently acquired by Nycomed.

44. In 1994, Nycomed acquired Sterling Winthrop's diagnostic imaging business.

45. In 1997, Nycomed acquired Amersham International plc, and the new company was named Amersham plc, which then held the rights to Omniscan.

46. In 2004, General Electric Company acquired Amersham plc and the rights to Omniscan.

47. At the time of the acquisition, Amersham plc was the ultimate parent company of Amersham Health AS, which manufactured the Omniscan that was distributed and sold in the United States, and Amersham Health Inc., which distributed and sold Omniscan in the United States.

48. In 2006, Amersham Health AS was renamed GE Healthcare AS, and Amersham Health, Inc. was renamed GE Healthcare, Inc.

49. Defendants General Electric Company, GE Healthcare AS, and GE Healthcare, Inc. are corporate successors to Amersham plc and its related entities, and, as such, are obligated for their predecessors' liabilities.

50. Amersham plc, either itself or by and through its subsidiaries, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

51. Omniscan is identified by General Electric Company in its packaging that it is a product of "GE Healthcare," which is a unit/division of General Electric Company.

52. "GE Healthcare" is prominently identified on the Omniscan packaging/prescribing information, alongside the "GE" monogram.

53. Omniscan is identified as a trademark of GE Healthcare.

54. "GE" and the GE monogram are trademarks of the General Electric Company.

55. The GE Healthcare website, which includes detailed product information concerning Omniscan, is copyrighted by General Electric Company.

56. General Electric Company has acknowledged in deposition testimony that GE Healthcare is not a separate entity from General Electric Company and that GE Healthcare is a unit of the General Electric Company that is responsible for Omniscan.

57. Subsidiaries obtaining revenue from the production and sale of Omniscan held revenue in a "lock box" and passed the revenue on to the General Electric Company.

58. General Electric Company does business as GE Healthcare, including the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce the drug Omniscan.

59. General Electric Company does business as GE Healthcare, including the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, the drug Omniscan.

60. At all times relevant, the GE Defendants, and/or their corporate predecessors, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

61. Upon information and belief and at the relevant times, Omniscan was distributed and sold in the United States, and the State of Texas, by the GE Defendants.

Magnevist and the Bayer Defendants

62. Magnevist is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography.

63. Magnevist is a patented, proprietary formulation that contains the metal gadolinium, which is highly toxic in its free state.

64. Magnevist, the chemical name of which is gadopentetate dimeglumine, is chemically distinct from other gadolinium-based contrast agents in that it more easily permits the release of toxic free gadolinium under expected physiologic conditions in patients with renal insufficiency who received it.

65. Magnevist (gadopentetate dimeglumine) is cleared from the body solely by glomerular filtration in the kidneys.

66. As a result, Magnevist has a prolonged half-life in patients with renal insufficiency.

67. Patients with renal insufficiency, therefore, are at increased risk for adverse health effects in connection with Magnevist (gadopentetate dimeglumine) administration.

68. Berlex obtained FDA approval of its New Drug Application (App. No. 019596) for Magnevist (gadopentetate dimeglumine) on June 2, 1988.

69. In 2006, Bayer AG, which has its legal domicile in Berlin, completed its acquisition of Schering, AG.

70. Berlex was a U.S. affiliate of Schering, AG.

71. Bayer AG is a holding company that owns and operates Defendant Bayer Healthcare Pharmaceuticals, Inc.

72. At all times relevant hereto, the Bayer Defendants knew or should have known about the significant health risk of Magnevist (gadopentetate dimeglumine) administration to patients with renal insufficiency including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs.

73. At all times relevant hereto, the Bayer Defendants knew or should have known that their product, Magnevist, was not reasonably fit, suitable or safe for its intended purpose, and specifically, that it was defective and unsafe for use in patients with renal insufficiency such as Gerald Hyde, and knew or should have known that the gadolinium contained in its product is highly toxic to humans.

74. Further, at all times relevant hereto, the Bayer Defendants knew or should have known about the significant health risk of Magnevist administration to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe and permanent physical injury.

75. The Bayer Defendants knew or should have known of the need to prevent the gadolinium contained in its product from becoming free in the body of humans injected with Magnevist through the use of, among other things, proper design, testing, and manufacturing.

76. At all times relevant hereto, the Bayer Defendants knew or should have known that there were safer, alternative designs for paramagnetic contrast agents that

would prevent or minimize the risk of gadolinium becoming free in the bodies of humans.

77. Notwithstanding their knowledge of the unreasonable dangers associated with Magnevist, this product was represented by the Bayer Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of cranial and spinal anatomy, as well as tumors, lesions, and immediately adjacent areas.

78. Magnevist was further represented by the Bayer Defendants to be superior to two of its competitors (Omniscan and OptiMARK) in its thermodynamic and conditional stability, its low volume of excess chelate, and its ability to prevent the release of gadolinium.

79. At all times relevant, the Bayer Defendants and/or their corporate predecessors, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the prescription drug Magnevist.

80. At all times relevant, the Bayer Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, and into the State of Massachusetts, either directly or indirectly through third parties or related entities, the diagnostic agent Magnevist.

OptiMARK and Mallinckrodt, Inc.

81. OptiMARK is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography.

82. OptiMARK contains the metal gadolinium, which is highly toxic in its free state.

83. OptiMARK, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethoxyethylamide (gadoversetamide), is represented by the Defendant Mallinckrodt to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

84. At all times relevant, Defendant Mallinckrodt was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agent OptiMARK.

MultiHance, ProHance and the Bracco Defendants

85. MultiHance and ProHance are injectable paramagnetic contrast agents for magnetic resonance imaging and arteriography.

86. MultiHance and Prohance contain the metal gadolinium, which is highly toxic in its free state.

87. Upon information and belief, MultiHance and ProHance were represented by the Bracco Defendants to be safely and effectively indicated for intravenous administration to facilitate visualization of lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues.

88. At all times relevant, the Bracco Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

89. At all times relevant hereto, the Defendants knew or should have known about the significant health risk of their products' administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs.

All Defendants

90. At all times relevant hereto, Defendants knew or should have known that, in its free state, gadolinium is highly toxic, harmful and dangerous to humans, and causes severe physical injury and knew or should have known of the need to prevent the gadolinium contained in its product from becoming free in the body of humans injected with Omniscan, Magnevist, OptiMARK, and/or, upon information and belief, MultiHance and/or ProHance, through the use of, among other things, proper design, testing, and manufacturing.

91. At all relevant times, Defendants knew or should have known that there were safer, alternative designs for paramagnetic contrast agents that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans and knew or should have known of safer, alternative designs for imaging systems, like those used by other leading MRI systems manufacturers, that do not use gadolinium-based contrast

agents, which would provide a safer imaging alternative for the public, including Gerald Hyde.

92. At all times relevant hereto, Defendants knew or should have known that their respective products, Omniscan, Magnevist, OptiMARK and/or upon information and belief, MultiHance and/or ProHance, were not reasonably fit, suitable or safe for their intended purpose and, specifically, that they were defective and unsafe for use in patients with renal insufficiency, such as Gerald Hyde, and knew or should have known that the gadolinium contained in its product is highly toxic to humans, and knew or should have known about the significant health risk of administration of these products to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe physical injury.

93. The condition of these products is one that would not be reasonably contemplated by an ordinary consumer.

94. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants consistently failed to warn consumers and/or their health care providers that severe, even fatal, injuries could result when their dyes are administered to patients with renal insufficiency.

95. During the years that the Defendants manufactured, marketed. and sold their respective products, there were numerous case reports, studies, assessments, papers, and other relevant experimental and clinical data that have described and/or demonstrated dissociation and transmetallation in connection with the use of certain gadolinium-based contrast agents.

96. Despite this, the GE, Bayer, Mallinckrodt and, upon information and belief, Bracco Defendants repeatedly failed to adequately revise their package inserts, Material Safety Data Sheets, and other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

97. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants repeatedly and consistently failed to advise consumers and/or their health care providers of the propensity of their products to undergo dissociation and transmetallation in vivo and of the causal relationship between certain gadolinium contrast dye and the development of NSF/NFD in patients with renal insufficiency.

98. Gerald Hyde suffered from renal insufficiency at all relevant times herein.

99. Gerald Hyde was exposed to the gadolinium-containing contrast dyes, upon information and belief, Omniscan, Magnevist, OptiMARK, ProHance and/or MultiHance, during imaging procedures in 2004.

100. After being administered, upon information and belief, Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, gadolinium was released into Mr. Hyde's body.

101. In June 2004, Gerald Hyde began to experience skin thickening and discoloration on his lower legs from what would ultimately be known as NSF, and suffered from debilitating and worsening fibrotic changes to his body as a result of contracting NSF/NFD which led to severe disfigurement, pain and suffering until the date of his death.

102. Gerald Hyde died on December 26, 2006 in the State of Massachusetts as the result of complications from NSF.

103. Gerald Hyde was not aware of any connection between his illness and gadolinium, and could not reasonably be aware of the connection, until advised of the connection in Spring 2006.

104. In fact, the connection was not known by the scientific community, other than those in the Defendants employ, until the FDA issued a black box warning in May 2007.

105. As a direct and proximate result of being administered Omniscan, Magnevist, OptiMARK, MultiHance, and/or ProHance in the context of his renal insufficiency, Gerald Hyde suffered serious, progressive, permanent, incurable, and fatal injuries.

106. As a direct and proximate result of being administered Omniscan, Magnevist, OptiMARK, MultiHance, and/or ProHance, Gerald Hyde sustained injuries and damages including, but not limited to, physical injury, bodily impairment, loss of enjoyment of life, disfigurement and scarring, severe and debilitating physical and emotional pain and distress, severely limited mobility, and, ultimately, death.

107. Gerald Hyde's spouse has also suffered loss of companionship, care and treatment, consortium, community, support, economic damages and all other damages recoverable by a spouse in the State of Massachusetts.

108. The Defendants, upon information and belief, have, or may have, failed to comply with all federal standards and requirements applicable to the sale of their

prescription drugs, Omniscan, Magnevist, OptiMARK, MultiHance and ProHance, including, but not limited to, one or more of the following violations:

a. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements;

b. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set forth in the official compendium for the drugs, and such deviation is not plainly stated on their labels;

c. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;

d. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

e. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or

the labeling does not bear adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users;

f. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

g. The Defendants' prescription drugs do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which they are intended, including conditions, purposes, or uses for which they are prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which they are intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate;

i. The Defendants' prescription drugs are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drugs, including degree and rate of absorption, pathways of biotransformation, percentage of dosage as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, and/or the degree of update by a particular organ;

k. The Defendants violated 21 CFR § 201.57 because evidence was only available to support the safety and effectiveness of the drugs in selected subgroups of the larger population with a disease, syndrome, or symptom and the labeling failed to describe the available evidence and state the limitations of usefulness of the drugs;

l. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drugs;

m. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drugs are such that the drugs should be reserved for certain situations, and the Defendants failed to state such information;

n. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur;

o. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug;

p. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drugs and other drugs in the same pharmacologically active and chemically related class;

q. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop NSF/NFD is significantly more severe than the other reactions listed in the adverse reactions, and, yet, the Defendants failed to list the development of NSF/NFD before the other adverse reactions on the labeling of the prescription drugs;

r. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose,

the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

s. The Defendants' prescription drugs violate 21 CFR § 210.1 because the process by which they are manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess;

t. The Defendants' prescription drugs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications;

u. The Defendants' prescription drugs violate 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

v. The Defendants' prescription drugs violate 21 CFR § 211.165 in that the prescription drugs fail to meet established standards or specifications and any other relevant quality control criteria;

w. The Defendants' prescription drugs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drugs were not followed;

x. The Defendants' prescription drugs violate 21 CFR § 310.303 in that the prescription drugs are not safe and effective for their intended use;

y. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are, or may be grounds for, suspending or withdrawing approval of the application to the FDA;

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drugs as soon as possible, or at least within 15 days of the initial receipt by the Defendants, of the adverse drug experience;

aa. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drugs and evaluating the cause of the adverse event;

bb. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information, or as requested by the FDA;

cc. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

dd. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up;"

ee. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drugs or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

ff. The Defendants violated 21 CFR § 312.32 because they failed to notify the FDA in a written IND safety report of the adverse experiences associated with the use of the prescription drugs that were serious and unexpected;

gg. The Defendants violated 21 CFR § 314.80 by failing to report adverse drug experiences at quarterly intervals for three (3) years from the date of approval of the application, and then at annual intervals;

hh. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

ii. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

FIRST CAUSE OF ACTION
Strict Products Liability--Defective Manufacturing: ALL DEFENDANTS

109. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

110. The GE Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Omniscan.

111. Defendant Mallinckrodt is the manufacturer, designer, distributor, seller, and/or supplier of OptiMARK.

112. The Bracco Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of MultiHance and ProHance.

113. The Bayer Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Magnevist.

114. Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, are diagnostic agents manufactured, designed, sold, distributed, supplied and/or, placed in the stream of commerce by Defendants, and were unreasonably dangerous and defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specifications, posing a serious risk of injury and death.

115. As a direct and proximate result of Gerald Hyde being administered Omniscan, OptiMARK, Magnevist, and/or upon information and belief, MultiHance and ProHance, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss from the use the contrast in question without the contrast undergoing substantial change.

SECOND CAUSE OF ACTION
Strict Products Liability--Design Defect: ALL DEFENDANTS

116. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

117. The Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance diagnostic agents manufactured and supplied by Defendants

were unreasonably dangerous and defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or they were more dangerous than an ordinary consumer would expect.

118. The foreseeable risks associated with the design or formulation of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, include, but are not limited to, the fact that the design or formulation of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

119. Defendants knew or should have known that there were safer, alternative designs for paramagnetic contrast agents, including non linear designs, that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans and knew or should have known that there were safer, reasonable alternative designs for imaging systems, like those used by other leading MRI systems manufacturers, that do not use gadolinium based contrast agents, which would provide a safer imaging alternative for the public, including Gerald Hyde.

120. As a direct and proximate result of Gerald Hyde being administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

THIRD CAUSE OF ACTION
Strict Products Liability–Defect Due to Inadequate Warning
ALL DEFENDANTS

121. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

122. The Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, manufactured and supplied by the GE Defendants, Defendant Mallinckrodt, Bayer Defendants, and Bracco Defendants respectively, were defective due to inadequate warning or instruction because Defendants had a duty to warn of defects and knew or should have known that their products created significant risks of serious bodily harm and death to consumers and they failed to adequately warn persons who were administered these products and/or their health care providers of such risks.

123. The Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance, Defendants failed to provide an adequate warning to users of these products and/or their health care providers, knowing the products could cause serious injury and death.

124. As a direct and proximate result of Gerald Hyde being administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and

ProHance, as manufactured, designed, sold, supplied and introduced into the stream of commerce by the Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

FOURTH CAUSE OF ACTION
Strict Products Liability—Defect due to Nonconformance with Representations
ALL DEFENDANTS

125. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

126. The GE Defendants, Defendant Mallinckrodt, Bayer Defendants and Bracco Defendants made representations regarding the character or quality of Omniscan, OptiMARK, Magnevist, MultiHance and ProHance, including representations that the Omniscan, OptiMARK, Magnevist, MultiHance and ProHance diagnostic agents were safe.

127. The Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents manufactured and supplied by Defendants were defective in that, when they left the hands of Defendants, they did not conform to representations made by Defendants concerning their products.

128. Gerald Hyde, and/or, Gerald Hyde's health care providers justifiably relied upon Defendants' representations regarding the Omniscan, OptiMARK, Magnevist and/or, upon information and belief, MultiHance and ProHance, diagnostic agents at the time those products were administered to him.

129. As a direct and proximate result of Gerald Hyde being administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

FIFTH CAUSE OF ACTION
Strict Products Liability--Defect Due to Failure to Adequately Test
ALL DEFENDANTS

130. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

131. Defendants advised consumers and the medical community that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance were safe for use. Defendants failed to adequately test Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, with respect to their use by consumers with renal insufficiency.

132. Had Defendants adequately tested the safety of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, for use by consumers with renal insufficiency and disclosed those results to the medical community or the public, Gerald Hyde would not have been administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and/or ProHance.

133. As a direct and proximate result of Gerald Hyde being administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance

and/or ProHance, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

SIXTH CAUSE OF ACTION
Strict Liability in Tort—ALL DEFENDANTS

134. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

135. Defendants used and controlled toxic gadolinium for injection in humans.

136. Gadolinium is highly toxic, inherently dangerous, and ultra-hazardous to humans.

137. Defendants allowed and directed that toxic gadolinium be used and injected in humans.

138. As a direct and proximate result of Defendants' use and control of toxic gadolinium, toxic gadolinium was injected and released into the body of Gerald Hyde and as a result, he suffered serious physical injury, death, harm, damages and economic loss.

139. Defendants are strictly liable for Gerald Hyde's injuries, damages and losses.

SEVENTH CAUSE OF ACTION

Negligence - Highest Possible Duty of Care
ALL DEFENDANTS

140. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

141. Because gadolinium is highly toxic and inherently dangerous and ultra-hazardous to humans, Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, sale and/or distribution of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents into the stream of commerce, including the duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

142. Defendants failed to exercise the highest possible degree of care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution into interstate commerce of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, in that Defendants knew, or should have known that their products were inherently dangerous and ultra-hazardous to humans, and caused such significant bodily harm or death and were not safe for administration to consumers.

143. Defendants also failed to exercise the highest possible degree of care in the labeling of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, OptiMARK, MultiHance, and Magnevist and ProHance.

144. Despite the fact that Defendants knew, or should have known that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, posed a serious risk of bodily harm to consumers, and was inherently dangerous and ultra-hazardous to humans and particularly those with renal insufficiency,

Defendants continued to manufacture and market Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

145. Defendants knew or should have known that it was foreseeable that consumers such as Gerald Hyde would suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

146. As a direct and proximate result of Defendants' negligence, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

EIGHTH CAUSE OF ACTION
Negligence—ALL DEFENDANTS

147. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

148. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, into the stream of commerce, including a duty to assure that their product did not pose a significantly increased risk of bodily harm and adverse events.

149. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution into interstate commerce of Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, in that Defendants knew or should

have known that the product caused such significant bodily harm or death and was not safe for administration to consumers.

150. Defendants also failed to exercise ordinary care in the labeling or warning for Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, OptiMARK, MultiHance, ProHance, and Magnevist.

151. Despite the fact that Defendants knew or should have known that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

152. Defendants knew or should have known that it was foreseeable that consumers such as Gerald Hyde would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

153. As a direct and proximate result of Defendants' negligence, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

NINTH CAUSE OF ACTION
Breach of Express Warranty—ALL DEFENDANTS

154. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

155. The GE Defendants, Defendant Mallinckrodt, Bracco Defendants and Bayer Defendants, expressly warranted that their products, Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, respectively, were safe and effective paramagnetic contrast agents for magnetic resonance imaging.

156. The Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, manufactured and sold by Defendants did not conform to these express representations because they caused serious injury when administered in recommended dosages.

157. As a direct and proximate result of Defendants' breach of warranty, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

TENTH CAUSE OF ACTION
Breach of Implied Warranty—ALL DEFENDANTS

158. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

159. At the time Defendants designed, manufactured, marketed, sold, and distributed Omniscan, OptiMARK, MultiHance, ProHance, and Magnevist, Defendants knew of the use for which Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, were intended and impliedly warranted their respective products to be of merchantable quality and safe for such use.

160. Gerald Hyde and his healthcare providers reasonably relied upon the skill and judgment of Defendants as to whether Omniscan, OptiMARK, Magnevist, and upon

information and belief, MultiHance and ProHance, were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

161. Contrary to such implied warranty, the Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents were not of merchantable quality or safe for their intended use because these products were unreasonably dangerous as described herein.

162. As a direct and proximate result of Defendants' breach of warranty, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

ELEVENTH CAUSE OF ACTION
Fraud/Misrepresentation—ALL DEFENDANTS

163. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

164. The GE Defendants, Defendant Mallinckrodt, Bracco Defendants and Bayer Defendants knowingly and intentionally made material, false and misleading representations to Gerald Hyde, his physicians, and to the public that their products, Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, respectively, were safe for use and that Defendants' labeling, marketing and promotion fully described all known risks of those products.

165. Specifically, the Defendants concealed or knowingly failed to advise consumers concerning the risk that highly toxic gadolinium would be released into the bodies of persons with renal insufficiency who were administered the product when they knew or should have known of that fact.

166. Defendants' representations were in fact false, as Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, are not safe for use and their labeling, marketing and promotion did not fully describe all known risks of those products, including the risk that highly toxic gadolinium would be released into the bodies of persons with renal insufficiency who were administered the product.

167. Defendants had actual knowledge based upon studies, published reports and clinical experience that their products, Omniscan, OptiMARK, MultiHance, ProHance, and Magnevist, created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

168. Defendants knowingly and intentionally omitted this information in their products' labeling, marketing, and promotion and instead, labeled, promoted and marketed their products as safe for use in order to avoid monetary losses and in order to sustain profits in their sales to consumers.

169. When Defendants made these representations that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, were safe for use, they knowingly and intentionally concealed and withheld from Gerald Hyde, his physicians and the public, the true facts that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents are not safe for use in consumers with renal insufficiency.

170. Defendants had a duty to disclose to Gerald Hyde, his physicians, and the public that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, were not safe for use in patients with renal insufficiency in

that they cause NSF/NFD, because they had superior knowledge of these facts that were material to Gerald Hyde's, and his physician's, decision to use Omniscan, OptiMARK, MultiHance, ProHance, and Magnevist.

171. Gerald Hyde and his physicians reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants' representations to Gerald Hyde and his health care providers, that the Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, diagnostic agents were safe for human consumption and/or use, and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

172. Had Gerald Hyde and his physicians known of Defendants' concealment of the true facts that Omniscan, OptiMARK, Magnevist, and upon information and belief, MultiHance and ProHance, were not safe for human use, Gerald Hyde would not have been administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance.

173. As a direct and proximate result of Defendants' misrepresentations and concealment, Gerald Hyde was administered Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance, Gerald Hyde suffered serious physical injury, death, damages and economic loss.

TWELFTH CAUSE OF ACTION
Negligent Misrepresentation—ALL DEFENDANTS

174. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

175. Defendants, in the course of their business profession, supplied Gerald Hyde, and his physicians, with false information for guidance in their decision to use Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance.

176. The false information supplied by Defendants to Gerald Hyde, and his physicians, was that Omniscan, OptiMARK, Magnevist, and/or, upon information and belief, MultiHance and ProHance, were safe and would not adversely affect Gerald Hyde's health, and in particular, the Defendants failed to advise Gerald Hyde, and Gerald Hyde's physicians, of the risk that highly toxic gadolinium would be released into the bodies of persons with renal insufficiency who were administered the product.

177. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Gerald Hyde and his physicians.

178. The false information obtained and communicated by Defendants to Gerald Hyde and his physicians was material, and they justifiably relied in good faith on the information given to them.

179. As a result of the negligent misrepresentations of Defendants, Gerald Hyde suffered serious physical injury, death, damages and economic loss as alleged herein.

THIRTEENTH CAUSE OF ACTION
Violation of the Massachusetts Consumer Protection Act
MGL ch. 93A et seq.

180. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

181. Plaintiff is a person within the meaning of the Massachusetts Consumer Protection Act (the "Act").

182. Defendants are persons within the meaning of the Act for all purposes therein.

183. Plaintiff is a person entitled to bring a claim pursuant to the Act.

184. The false, deceptive and misleading statements and representations made by Defendants alleged above are Deceptive Acts or Practices within the meaning of the Act.

185. Defendants engaged in the Deceptive Trade Practices alleged above, and those Deceptive Trade Practices occurred or were committed in the course, vocation or occupation of Defendants' pharmaceutical business.

186. The Deceptive Trade Practices that Defendants committed as alleged above significantly impacts the public as actual or potential customers of Defendants.

187. As a direct and proximate result of the Deceptive Trade Practices committed by Defendants as alleged above, Plaintiff suffered injuries, damages and losses as alleged herein.

188. Plaintiff is entitled to recover all damages permitted by ALM GL ch. 93A, Sec. 9 of this Act, including actual damages sustained, double or treble damages, civil penalties, attorneys' fees and costs of this action.

FOURTEENTH CAUSE OF ACTION
Wrongful Death
ALL DEFENDANTS

189. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

190. Gerald Hyde developed NSF as a result of being exposed to gadolinium contrast dye designed, manufactured and/or put into the stream of commerce by Defendants.

191. As a direct and proximate result of his NSF, Gerald Hyde suffered severe health impairment and complications that ultimately led to his death.

192. Plaintiff Beverly Hyde is the widow and Executrix of the Estate of Gerald Hyde.

193. Plaintiff suffered economic and non-economic damages, as described herein, a loss of companionship and consortium as a direct and proximate result of Defendants' actions.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to, pain, suffering, emotional distress, loss of enjoyment of life, emotional distress, disfigurement, permanent physical impairment and other non-economic damages in an amount to be determined at trial of this action;

2. Expenses, income, and other economic damages in an amount to be determined at trial of this action;

3. Loss of consortium, community and companionship damages and all other damages afforded Beverly Hyde, as widow of Gerald Hyde, under the laws of Massachusetts;

4. All statutory damages, including, but not limited to, treble damages;

5. Punitive damages;

6 Pre- and post-judgment interest;

7. Attorneys' fees, expenses, and costs of this action as allowed by law; and

Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted this 24th day of February, 2009.

By: Michael R. Hugo

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